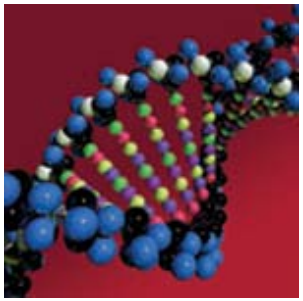
Evidence-based decision making and tobacco harm reduction modeling: Opportunities and Barriers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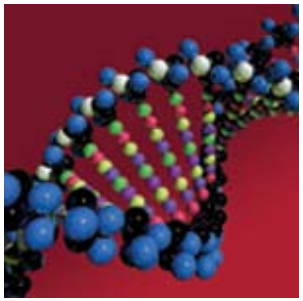
Outline

1. Definitions
   - Evidence-based decision making
   - Tobacco Harm Reduction (THR)
   - Individual vs. population level effects
2. THR and rationale for modeling
3. Barriers and opportunities afforded by modeling
4. Summary, discussion/questions

1. Definitions


Evidence-based decision making

- Entails "…conscientious, explicit and judicious use of current best evidence…" (David Sackett)
- Current, popular concept in various settings
  - Clinical medicine
  - Policy development
  - Program formulation & evaluation
- Aims to make decision process transparent, increase objectivity
- Promotes
  - Critical assessment of available data
  - Identification of data gaps
  - Discussion (theoretically)

Features of evidence-based decisions

- Specifies
  - Underlying assumptions
  - Sources of information
- Underlying logic can be examined
- Can assess effect of
  - Changes to assumptions
  - Application of new, different data

How else are decisions made?

- Depends on setting, context
  - Discussion/consensus
  - Majority opinion (voting)
  - Authority
  - Intuition/judgment
- These approaches have their place
- Is their place in science, medicine, or policy/program development & evaluation?

Tobacco Harm Reduction

- Construct: Reducing exposure to certain tobacco constituents leads to fewer health effects
- THR may be achieved by
  - Individuals reducing the number of cigarettes smoked
  - Cigarette design modification (e.g., low tar products)
  - Product substitution (e.g., SLT, snüs, PREPs)

Individual vs population THR benefits

- Individual benefits of THR include, for example:
  - Reduced risk of disease
  - Reduced duration, severity of disease
- Population benefits of THR include, for example:
  - Reduced number of sick people
  - Less time sick
  - Economics: increased productivity, decreased medical care costs
- Population level benefits may outweigh individual benefits (policy implications)

Example: individual vs. population effects

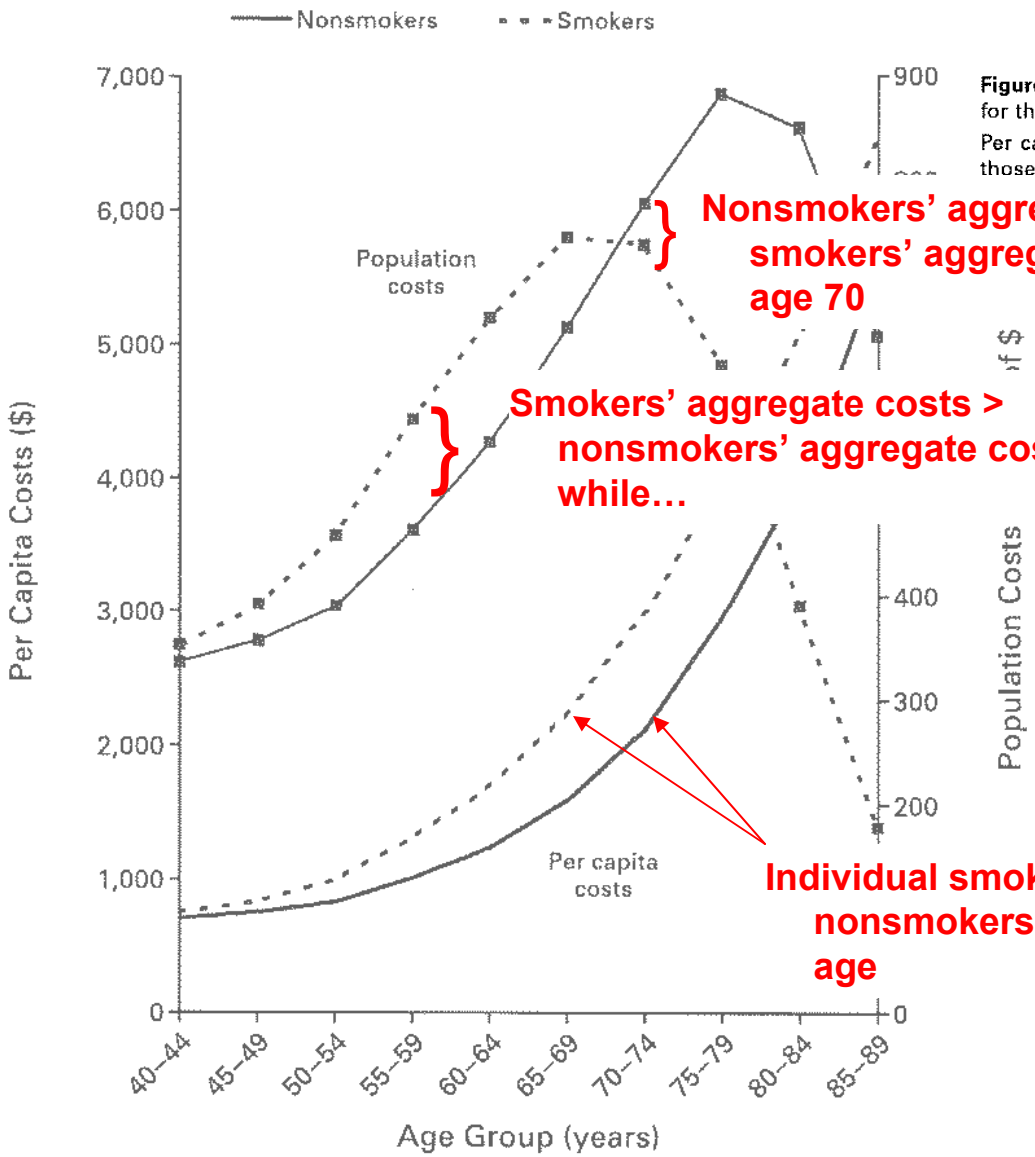


Figure 1. Estimated Annual per Capita Health Care Costs for Dutch Men in 1988 and for the Male Population in a Life Table, According to Age and Smoking Status.
Per capita health care costs for women in the same age groups are very similar to those for men.

EJM 337:1052-1057

Nonsmokers' aggregate costs > smokers' aggregate costs after about age 70

Smokers' aggregate costs > nonsmokers' aggregate costs for a while…

Individual smokers' costs > nonsmokers' costs at every age

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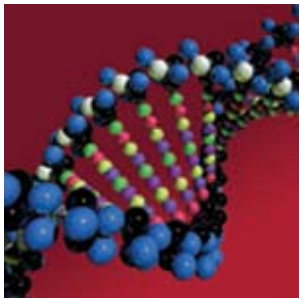
2. THR and rationale for modeling


Some arguments used against THR

- "Reduced harm" might be misinterpreted as "safe"
- Some smokers might be dissuaded from quitting
- Some individual smokers will not benefit
  - Not all tobacco constituents reduced
  - Not all health outcomes affected
- THR products might serve as "gateways" to cigarettes
- Society "should not" tolerate tobacco use in any form

Some arguments used for THR

- Individual users have the right to choose less harmful products
- Some individual users will experience health benefits
- ETS will be reduced or removed
- THR products might assist users in quitting
- At the population level, THR likely to reduce tobacco-associated health effects

THR: Non-human evidence

- Toxicology studies measure effect of exposure in non-human species
- Product composition data compare levels of specific constituents in different products
- Generally suggest reduced harm, but
  - Not directly applicable to population-level or individual human health questions
  - Require extrapolations that might not be valid
- Can be used to formulate hypotheses re: human effects

THR: Human evidence

- Comparisons of health effects among groups of users
  - Observational epidemiological studies
  - Forced switching studies
- All generally show reduced risk
- Methodological, interpretational limitations
- PREPs have not been available long enough, widely enough to study

Rationale for THR models

- Long term epidemiological studies ideal, but not expedient
- Existing data inadequate to answer critical questions
- Modeled effects can be compared to results of epidemiological studies when data become available
- Models support decision-making in the short run

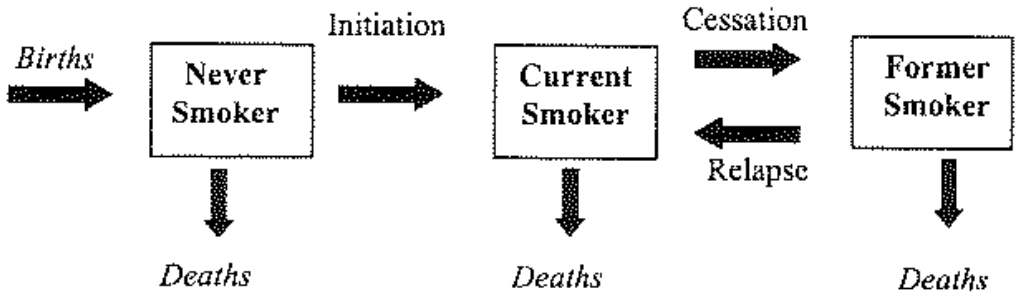
What is a model?

"a simplified representation of a system or phenomenon, as in the sciences or economics, with any hypotheses required to describe the system or explain the phenomenon, often mathematically"

(*Dictionary.com Unabridged (v 1.1), Based on the Random House Unabridged Dictionary, © Random House, Inc. 2006.*

Examples of THR models

- Schematic:



- Mathematical:

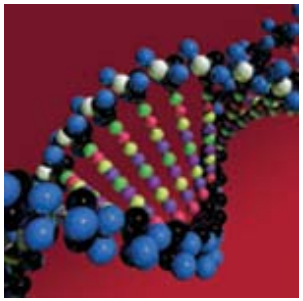
$$i_{d,base}(a) = \frac{i_{d,0}(a)}{\sum_c RR_d(c,a) n_{c,0}(a)}$$

Hoogenveen et al. 2008; Cost Effect Resource Alloc 6(1). http://www.resource-allocation.com/content/6/1/1

THR models require data

- Description of target population √
- Specification of products to be assessed √
- Specification of outcome – individual disease(s), life expectancy, healthy life expectancy, etc. (√)
- Exposure prevalence, each product
- Rates of uptake, quitting, switching, re-uptake
- Relative risk or risk difference
- Rate of risk change over time

3. Barriers and opportunities afforded by modeling


Barriers to developing THR models

- Models, by definition, are simplistic
  - Populations, risks, tobacco use states are dynamic
  - Diseases have multiple causes
  - “Health” hard to define
- Need reasonable estimates, assumptions
  - Exposure prevalence, each product
  - Rates of uptake, quitting, switching, recidivism
  - Relative risk or risk difference
  - Rate of risk change over time after changing habit
- Challenging (social) climate

Opportunities offered by THR models

- High level of scrutiny may increase rigor, quality of work
- Specification of underlying assumptions should promote healthy discussion, critical evaluation
- Modeled results can be validated against other modeling approaches, observational data
- Models can be revised as new data become available
- Pragmatic approach to evaluating products that might reduce harm to consumers
- Promotes rational, evidence-based decision-making

Reminder

Evidence-based decisions entail:

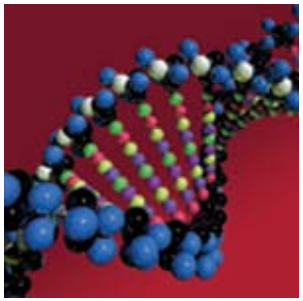
"…conscientious, explicit and judicious use of current best evidence…"

(David Sackett)

Opportunities offered by THR research

- Various sectors join to generate, share and critically evaluate data
- Open the discussion
- Promote rational decision making by all sectors
  - Consumers
  - Producers
  - Policy makers

4. Summary, questions/discussion


Summary

Although there are significant scientific, social barriers,

- Individual and group-level decisions have to be made
- The process should be transparent, logical
- Existing data are inadequate support decisions
- Observational studies must be done, but may take decades
- Models can support decision making in the short run, can be modified with new data, refined assumptions

Discussion/questions?